

REMARKS

Claims 27-32 and 48 were examined. Claim 27 is amended. Claims 49-50 are added. Claims 27-32 and 48-50 remain in the Application.

The Patent Office rejects claims 27-30 and 48 under 35 U.S.C. §112, first paragraph. The Patent Office rejects claims 27-32 and 48 under 35 U.S.C. §102(b). Reconsideration of the pending claims is respectfully requested in view of the above amendments and the following remarks.

A. 35 U.S.C. §112, First Paragraph: Rejection of Claims 27-30 & 48

The Patent Office rejects claims 27-30 and 48 under 35 U.S.C. §112, first paragraph, because the specification, while enabling for a poly (amino acid) delivery system, does not reasonably provide enablement for any delivery carrier.

Applicant respectfully asserts that the Application provides enablement for various types of delivery carriers. For example, at page 19, lines 8-18, a number of different barriers are taught that are not literally poly (amino acid). For example, these barriers include "pseudo"-poly (amino acids), ionic barriers, polymers and protein.

Applicant respectfully requests that the Patent Office withdraw the rejection of claims 27-30 and 48 under 35 U.S.C. §112, first paragraph.

B. 35 U.S.C. §102(b): Rejection of Claims 27-32 & 48

The Patent Office rejects claims 27-32 and 48 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,458,387 of Scott et al. (Scott). Scott is cited for teaching a complexing agent or binding member. Reference is made to column 5, lines 25-34. The complexing agent, according to the Patent Office, is capable of ionic interaction with a therapeutic agent.

Independent claim 27 is not anticipated by Scott, because Scott does not describe a method including delivering a treatment agent to a tissue, the treatment agent within a barrier, wherein the barrier has a binding member and a delivery carrier. The binding member of the

barrier has a property adapted to couple to a surface of the tissue. The barrier is present in an amount sufficient to permit transport of the treatment agent from the tissue at a lower rate than transport in the absence of the barrier component.

In a particularly preferred aspect, Scott describes a microsphere including at least two complexing agents. The complexing agents include a macromolecule such as a carrier protein (e.g., albumin); at least one water soluble polymer (e.g., hetastarch PEG/PVP); a first complexing agent that is an anionic polysaccharide; and a second complexing agent that is a divalent cation. See col. 5, lines 24-37. "[A] complexing agent refers to a molecule which is capable of interacting with a therapeutic agent (discussed below) to facilitate loading, retaining and/or otherwise delaying the release of the therapeutic agent from the microsphere (see, e.g., Table 3)." Col. 5, lines 38-42. Thus, the complexing agent(s) are intended to bind or otherwise interact with the therapeutic agent or with another complexing agent. See col. 5, lines 54-60. The complexing agents are not described as having a property adapted to couple to a surface of a tissue.

Claims 28-32 and 48 depend from claim 27 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 27, claims 28-32 and 48 are not anticipated by Scott.

Applicant respectfully requests that the Patent Office withdraw the rejection of claims 27-32 and 48 under 35 U.S.C. §102(b).

C. Additional Claims 49-50

Applicant adds claims 49-50. Support for claim 49 may be found in the Application at, page 15, line 23 through page 16, line 2. Support for claim 50 may be found in the Application at page 16, lines 3-9.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

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